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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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John Graeme Houston

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EXAMINER

AUGHENBAUGH, WALTER

ART UNIT

PAPER NUMBER

1772

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

04/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/650,217	HOUSTON ET AL.	
	Examiner	Art Unit	
	Walter B. Aughenbaugh	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2007 and 24 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-37 and 47-54 is/are pending in the application.
- 4a) Of the above claim(s) 50-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-37, 47-49, 53 and 54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgement of Applicant's Amendments

1. The amendments made in claims 33, 34, 37, 47 and 49 in the Amendment filed January 12, 2007 (Amdt. A) have been received and considered by Examiner.
2. New claims 53 and 54 presented in Amdt. A have been received and considered by Examiner.

WITHDRAWN REJECTIONS

3. The 35 U.S.C. 112, first paragraph, rejection of claim 33 made of record in paragraph 3 of the previous Office Action mailed March 24, 2006 has been withdrawn due to Applicant's amendment in claim 33 in Amdt. A.
4. The 35 U.S.C. 112, second paragraph, rejection of claims 33 and 49 made of record in paragraph 5 of the previous Office Action mailed March 24, 2006 has been withdrawn due to Applicant's amendments in claims 33 and 49 in Amdt. A.

REPEATED REJECTION

Claim Rejections - 35 USC § 102

5. The 35 U.S.C. 102 rejection of claims 33-37 and 47-49 made of record in paragraph 7 of the previous Office Action mailed March 24, 2006 has been repeated for the reasons previously made of record, and for the following reasons that address the amendments in claims 33, 34, 37, 47 and 49 in Amdt. A: in regard to claim 33, Frassica teaches that the stent comprises a mesh member (col. 5, lines 40-46) and that the mesh member has an internal helical formation (coiled sidewall reinforcement member, item 310, Fig. 17, col. 19, lines 34-36). Since the internal helical formation (coiled sidewall reinforcement member, item 310) is arranged spirally around

Art Unit: 1772

the interior of the mesh member (Fig. 17), the coiled sidewall reinforcement member, item 310, induces spiral flow through the interior of the stent.

In regard to claim 34, Frassica teaches that the mesh member is expansible (col. 5, lines 40-46).

In regard to claim 37, the spiral flow inducer vane (thread, item 303) surrounds the rigid support (the wall of the stent) and extends from the rigid support (the wall of the stent) and that the vane has an adjustable helix angle (col. 19, lines 21-26 and Fig. 16 and 17).

In regard to claim 47, Frassica teaches an intravascular stent (col. 19, lines 19-41) comprising an expansible tubular mesh member having a collapsed form to be inserted into a vein (col. 5, lines 40-46) and an expanded form to be retained within the vein (col. 5, lines 40-46).

In regard to claim 49, Frassica teaches that the stent comprises a rigid support rod (coiled sidewall reinforcement member, item 310), a flexible sleeve (tube, item 302) surrounding the support rod and a flexible helical vane (thread, item 303) mounted to the sleeve (col. 19, lines 19-36 and Fig. 16 and 17). The sleeve of Frassica is axially contractible relative to the support rod since Frassica teaches that it is expandable by design (col. 5, lines 40-44). Axially contracting the stent necessarily varies the angle of the vane (thread, item 303, Fig. 16 and 17, and col. 5, lines 40-44).

NEW REJECTIONS

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

7. Claim 53 is rejected under 35 U.S.C. 102(b) as being anticipated by Frassica (USPN 5,989,230). The helix angle of the spiral flow inducer vane (thread, item 303) falls within the claimed range of between about 5 degrees and about 50 degrees (Fig. 16).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Frassica (USPN 5,989,230).

Frassica teaches the stent as discussed above in regard to claim 37. The spiral flow inducer vane (thread, item 303) is shown having a particular helix angle in Fig. 16. Frassica teaches that the ratio of the thread pitch to the circumference of the thread diameter is less than 1:1 (col. 19, lines 21-26). Frassica teaches that the spiral arrangement of spiral flow inducer vane

Art Unit: 1772

(thread, item 303) facilitates advancement of the stent through a passageway via rotational advancement (col. 19, lines 19-27 and 36-41 and col. 11, lines 43-49).

Frassica fails to explicitly teach that the helix angle of the spiral flow inducer vane (thread, item 303) is about 16 degrees.

Since Frassica teaches that the spiral arrangement of spiral flow inducer vane (thread, item 303) facilitates advancement of the stent through a passageway via rotational advancement (col. 19, lines 19-27 and 36-41 and col. 11, lines 43-49) and that the ratio of the thread pitch to the circumference of the thread diameter is less than 1:1 (and therefore Frassica teaches variation of the helix angle), one of ordinary skill in the art would have recognized to have varied the helix angle of the spiral flow inducer vane (thread, item 303) to achieve the optimal rotational advancement of the stent in terms of ease of advancement depending on the particular desired end result since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. MPEP 2144.05 II.B.

Response to Arguments

10. Applicant's arguments presented on pages 5-9 of Amdt. A regarding the 35 U.S.C. 102 rejection of claims 33-37 and 47-49 have been fully considered but are not persuasive.

In regard to claim 34, the stent taught in col. 19 of Frassica comprises a mesh member by virtue of the fact that it is a stent: Frassica teaches that stents comprise a mesh member at col. 5, lines 40-46. The text of col. 5, lines 45-47 of Frassica is not stated to be a problem by Frassica. Frassica teaches that stents are intended to "anchor in place" (col. 5, lines 44-45). It is desirable that the stent be relatively easily advanced through a passage passageway via rotational advancement (col. 19, lines 19-27 and 36-41 and col. 11, lines 43-49) to advance the stent to the

Art Unit: 1772

location it needs to be advanced to depending on the particular desired end result, but once the stent has reached this location, it is then desirable that the stent “anchor in place” so it can perform the function that it is intended to perform (col. 5, lines 40-47). Applicant’s statement that reduction of urine flow is a problem is unsupported. Applicant’s statement that ingrowth of tissue in the stent (once the stent is advanced to the location it needs to be advanced to depending on the particular desired end result) is a problem is unsupported: it is desirable that the stent “anchor in place” so it can perform the function that it is intended to perform (col. 5, lines 40-47).

Coiled sidewall reinforcement member, item 310, Fig. 17, is an internal helical formation (col. 19, lines 34-36). Since the internal helical formation (coiled sidewall reinforcement member, item 310) is arranged spirally around the interior of the mesh member (Fig. 17), the coiled sidewall reinforcement member, item 310, induces spiral flow through the interior of the stent. Applicant’s statements that coiled sidewall reinforcement member, item 310, “would not induce spiral flow...” and “... becomes turbulent flow rather than helical or spiral flow” are unsupported.

In regard to claim 37, the spiral flow inducer vane (thread, item 303) surrounds the rigid support (the wall of the stent) and extends from the rigid support (the wall of the stent) and that the vane has an adjustable helix angle (col. 19, lines 21-26 and Fig. 16 and 17). Frassica teaches that the ratio of the thread pitch to the circumference of the thread diameter is less than 1:1 (col. 19, lines 21-26), which is a teaching of variation of the helix angle. The rejection of record (as updated in this Office Action as a result of Applicant’s amendment in claim 37 in Amdt. A) does

Art Unit: 1772

not state that the helix angle of the coiled sidewall reinforcement member, item 310, is adjustable.

The basis for rejection of claim 49 has been updated in this Office Action as a result of Applicant's amendments in claim 49 in Amdt. A.

Applicant's arguments regarding the rejection of claim 33 are applicable to Applicant's arguments regarding the rejection of claim 47.

In regard to claim 48, the claimed structure falls within the scope of mesh structures delineated by the recitation of claim 48. Applicant has admitted this by arguing that there is a single arrangement that does not fall within the scope of the structure claimed in claim 48.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1772


12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is (571) 272-1488. While the examiner sets his work schedule under the Increased Flexitime Policy, he can normally be reached on Monday-Friday from 8:45am to 5:15pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on (571) 272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Walter B. Aughenbaugh
03/29/07

WBA


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SUPERVISORY PATENT EXAMINER
3/31/7